

REMARKS

In an Advisory Action mailed 12/31/08, the Examiner indicated that claims 124, 127, 132-135, 137, and 138 were allowed and that the Amendment filed 12/15/08 would have rendered claims 126, 129, 144, and 145 allowable if it had been entered. Claims 125, 128, 150, and claims dependent thereon remained rejected. In the instant Response, Applicants amend claims 126, 129, 144, and 145 as in the non-entered Amendment filed 12/15/08 (with minor corrections) and cancel claims 123 and 163.

Applicants and their representatives thank the Examiner for the courtesy of a telephonic interview conducted on Feb. 4, 2009, with Eric Brusca and Monica Gerber (representing the assignee) and for her helpful comments and suggestions. The present response addresses the substantive points discussed during the interview. Among other things (i) the distinction between claims 125 and 128 versus claims 124 and 127; (ii) the term “substituent” in claim 150; and (iii) the withdrawn claims to fibers and polymers were discussed. Agreement was reached on these and other issues, as described below. Accordingly, the present response is believed to constitute a complete written statement of the reasons presented in the interview as warranting favorable action, in accordance with 37 C.F.R. §1.133.

In the instant response, in addition to the amendments discussed above, claims 67, 101, and 148 have been amended to depend on allowed claims 124 or 127. Claim 150 has been amended so that the claim is now drawn to polypeptides comprising a SCHAG amino acid sequence as recited in claim 124 or 127 and having at least one moiety attached to a side chain of the SCHAG polypeptide, as discussed during the interview. Claims 81, 103, 105, 106, 147, and 149, which had been withdrawn from consideration, have been cancelled. No new matter is introduced. The amendments herein should not be construed as acquiescing in the rejections. Applicants reserve the right to pursue claims of similar or different scope in one or more continuing applications.

Applicants respectfully request entry of the amendments set forth above and reconsideration and withdrawal of the restriction requirement and all remaining objections and rejections in view of the amendments and the following remarks.

Restriction Requirement

During the interview the Examiner indicated that the restriction requirement would be withdrawn as to claims to polymers and fibers, and that claims to polymers or fibers comprising polypeptides as set forth in the allowed claims would be allowable. Applicants have accordingly amended claims 67, 101, and 148 to depend on claims 124 and 127 and have cancelled claims 81, 103, 105, 106, 147, and 149. Applicants respectfully note that claims 67, 101, 148, and 156 all recite a moiety attached to a side chain of an amino acid, but that the lists of moieties differ. For example, the list of moieties recited in claim 67 does not include “hormone”, the list of moieties recited in claim 101 does not include “cell adhesion molecule”, and the list of moieties recited in claim 148 does not include “chromatic dye”. Applicants respectfully request that the restriction requirement be withdrawn and the pending claims to fibers and polymers be allowed.

Rejections under 35 U.S.C. 112, second paragraph

Claims 123, 125, 126, 128, 129, 139-140, 144, 145, 150-155, 157-161 and 163 stand rejected under 35 USC 112, second paragraph as allegedly being indefinite for reasons described in the Office Action. Applicants have canceled claims 123 and 163 and have amended claims 125, 126, 128, 129, 144, 145, 150-152, 154, 157, 159, and 161 as described below:

Claims 125 and 128 were rejected as allegedly unclear for reciting “exactly one amino acid”. Claim 125 has been amended to recite that the SCHAG amino acid sequence comprises an amino acid with a reactable side chain selected from the group consisting of cysteine, lysine, glutamate, aspartate, and arginine substituted for the amino acid present at position 2 of SEQ ID NO: 2, and said amino acid substituted at position 2 of SEQ ID NO: 2 is the only amino acid with a reactive side chain present in the SCHAG amino acid sequence. Claim 128 has been amended to recite that the SCHAG amino acid sequence comprises an amino acid with a reactable side chain selected from the group consisting of cysteine and arginine substituted for the amino acid present at position 184 of SEQ ID NO: 2, and said amino acid substituted at position 184 of SEQ ID NO: 2 is the only amino acid with a reactive side chain present in the SCHAG amino acid sequence.

As discussed during the interview, claims 125 and 128 are distinct from claims 124 and 127, respectively, at least because claims 124 and 127 encompass embodiments in which the SCHAG amino acid sequence comprises more than one amino acid with a reactive side chain, whereas claims 125 and 128 require that the SCHAG amino acid sequence comprises exactly one amino acid with a reactive side chain. For example, the SCHAG amino acid sequence of claim 124 or claim 127 could comprise two cysteines, while the SCHAG amino acid sequence of claim 125 or claim 128 could comprise at most one cysteine.

During the interview the Examiner requested that Applicants point to support in the specification for claims 125 and 128 in their response and to confirm that the SCHAG amino acid sequences of claims 125 and 128 satisfy the requirement of being at least 90% identical to amino acids 2 to 113 of SEQ ID NO: 2 or amino acids 2-253 of SEQ ID NO: 2, respectively, as recited in parent claims 124 and 127. Accordingly, Applicants respectfully direct the Examiner to p. 27, line 18 – p. 28, line 2, which state: “In a highly preferred embodiment, the SCHAG amino acid sequence is modified to contain exactly one, two, three, four, or some other specifically desired number of the reactive amino acids, thereby providing a SCHAG amino acid sequence which is modifiable at controlled, stoichiometric levels and positions. To achieve this goal, modifications to remove undesirable, native reactive amino acids from a naturally occurring SCHAG sequence are contemplated. Polypeptides comprising a naturally occurring SCHAG amino acid sequence characterized by one or more reactive amino acids, that have been modified by substituting or eliminating a natural reactive amino acid, are considered a further aspect of the invention, as are polynucleotides that encode the polypeptides.” The specification thus clearly discloses embodiments in which the SCHAG amino acid sequence is modified to remove reactive amino acids if multiple reactive amino acids are originally present.

To show that the claimed amino acid sequences are at least 90% identical to amino acids 2 to 113 of SEQ ID NO: 2 or amino acids 2-253 of SEQ ID NO: 2, amino acids 1-253 of SEQ ID NO: 2 are shown below for purposes of convenience, wherein amino acid 113 (Y 113) is boldface and underlined.

MSDSNQGNQQNYQQYSQNGNQQQGNNRYQGYQAYNAQAQPAGGYYQNYQGYSGYQQGGY
QQYNPDAGYQQQYNPQGGYQQYNPQGGYQQQFNPQGGGRGNYKNFNYNNNLQGYQAGFQQ
SQGMSLNDFQKQQKQAAPPKKTLKLVSSSGIKLANATKVGTKPAESDKKEEKSAETK
EPTKEPTKVEEPVKKEEKPVQTEEKTEELPKVEDLKISESTHNTNNANVTSADALIK
EQEEEVDEVVND

The table below lists the number of times that various amino acids recited in claims 124 and 127 occur within the indicated portions of SEQ ID NO: 2. “Not relevant” is used to indicate that the listed amino acid is not recited in the claim.

Amino acid	No. of occurrences in AA 2-113 (relevant to claims 124 and 127)	No. of occurrences in AA 2-253 (relevant to claims 125 and 128)
Cysteine (C)	0	0
lysine (K)	1	Not relevant
glutamate (E)	0	Not relevant
aspartate (D)	2	Not relevant
arginine (R)	2	2

It is readily seen that cysteine and glutamate are entirely absent; there is one lysine within amino acids 2-113, there are two aspartates within amino acids 2-113, and there are two arginines within amino acids 2-253. Thus any modifications required to meet the limitations of claims 125 and 128 will not bring the SCHAG amino acid sequence outside the range of 90% identity to amino acids 2-113 or 2-253 of SEQ ID NO: 2, respectively, recited in parent claims 124 and 127.

Claims 126 and 129 were rejected as allegedly vague and ambiguous for reciting “wherein the amino acid with a reactable side chain is a cysteine or glutamate residue”. Applicants respectfully disagree but for purposes of consistency with the language of claims 124 and 127, the word “residue” has been deleted as suggested by the Examiner.

With respect to claims 144 and 145, in order to advance prosecution the claims have been amended to recite “polypeptide”, consistent with the other claims. During the interview the Examiner requested clarification as to how claims 144 and 145 differ from claims 124 and 127. Claims 144 and 145 differ in scope from claims 124 and 127 in that claim 124 recites a SCHAG amino acid sequence that is at least 90% identical to *amino acids 2 to 113* of SEQ ID NO: 2 and claim 127 recites a SCHAG amino acid sequence that is at least 90% identical to *amino acids 2 to 213* of SEQ ID NO: 2, whereas claims 144 and 145 recite polypeptides that comprise a sequence at least 90% identical to the *complete SCHAG amino acid sequence* of SEQ ID NO: 2 (which is 685 amino acids in length). Thus claims 124 and 127 encompass numerous polypeptides that are not within the scope of claims 144 or 145.

Claim 150 was rejected as allegedly vague and ambiguous for reciting a polypeptide with “at least one substituent attached to a side chain of the SCHAG amino acid sequence...” During the interview the Examiner indicated that replacing the term “substituent” with an alternate term such as “moiety” would clarify that the substituent is not a substitution within the SCHAG amino acid sequence, i.e., the substituent is not substituted as a replacement for the amino acid with the reactable side chain. Applicants continue to maintain that in the context of claim 150 and in light of the specification, one of skill in the art would understand that the term “substituent” is used to denote a “moiety” or “entity” attached to the side chain rather than a replacement of an amino acid within the SCHAG amino acid sequence, but have amended claim 150 and claims dependent thereon herein to recite “moiety” rather than “substituent”, thereby obviating the rejection.

Claims 152-154, 159-161, and 163 were rejected as allegedly indefinite for reciting attachments of substituents to different amino acids within SEQ ID NO: 2 while claim 150 was allegedly limited to the polypeptide of SEQ ID NO: 2 with no substitutions. Applicants respectfully disagree but submit that the rejection has been rendered moot by the instant amendment. The SCHAG amino acid sequence of claim 150 need only be at least 90% identical to amino acids 2-113 of SEQ ID NO: 2 or at least 90% identical to amino acids 2-253 of SEQ ID NO: 2, and the “substituents” are not “substitutions” within the polypeptide but rather are moieties attached to side chains of amino acids of the polypeptide.

Claim 158 was rejected as allegedly lacking antecedent basis for the recitation “two different substituents”. Applicants respectfully disagree that this phrase requires antecedent basis but have amended the claim to recite that “the polypeptide comprises at least two moieties attached to side chains of the polypeptide, wherein the moieties are different”. Support is found, e.g., at p. 28, lines 9-12, which state, “Also contemplated are polymers or fibers that comprise more than one type of substituent by attachment of different substituents to the reactable SCHAG amino acid sequence of the polypeptide subunits of the polymer or fiber.”

Claims 123, 139, 140, 151, 155, and 157 were rejected as allegedly indefinite for being dependent on indefinite claims. Claim 123 has been canceled. Applicants respectfully submit that the allegedly indefinite claims on which claims 139, 140, 151, 155, and 157 depend (i.e., claims 144, 145, and 150) have been amended as indicated above, thereby obviating the rejection.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC 112, second paragraph.

Rejections under 35 U.S.C. 103

Claims 150, 151, 155, and 157 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Kushnirov, et al., 1988 (Gene, 66, pp. 45-54). While Applicants respectfully disagree with the rejection, solely in the interests of advancing prosecution Applicants have amended claim 150 such that the claim is now directed to polypeptides as recited in claim 124 or claim 127 that have a moiety selected from the group consisting of an enzyme, a metal atom, an affinity binding molecule having a specific affinity binding partner, a carbohydrate, a fluorescent dye, a chromatic dye, an antibody, a growth factor, a hormone, a cell adhesion molecule, a toxin, a detoxicant, a catalyst, a light-harvesting substituent, and a light altering substituent attached to a side chain of the SCHAG polypeptide. Applicants respectfully submit that claimed subject matter does not encompass naturally occurring Sup35. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In conclusion, Applicants respectfully submit that the instant amendment places the application in condition for allowance. Applicants respectfully request that the restriction requirement, objection, and rejections be withdrawn and that the claims be allowed.

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Respectfully submitted,


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